

***510(k) Summary of Safety and Effectiveness
Ambulatory Blood Pressure
92506 Report Management System***

Proprietary: Ambulatory Blood Pressure (ABP) 92506 Report Management System (RMS)
 Common: Noninvasive blood pressure measurement system, accessory
 Classification: Class II – 21 CFR §870.1130
 Panel: Cardiovascular
 Contact Person: Al Van Houdt, Director of Regulatory Affairs and Quality

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 1992.

The Spacelabs Medical ABP 92506 Report Management System (RMS) is substantially equivalent to the following currently marketed device(s):

Spacelabs Medical Ambulatory Blood Pressure Monitor (includes 90219 RMS)	K855127
Spacelabs Medical Ambulatory Blood Pressure Monitor (includes 90121 RMS)	K855127 (Letter to File)

The Spacelabs Medical ABP 92506 RMS is a PC-based software application that accepts data collected from one of Spacelabs Medical’s ABP monitors through an electrically-isolated interface cable.

The ABP 92506 RMS has a graphical user interface (GUI) similar to most Microsoft applications such as Word, Excel, etc. that provides common windowing controls such as menus, icons, mouse support, wizards, etc. These controls allow the operator to communicate with the ABP monitor.

Additionally, the ABP 92506 RMS provides necessary initialization and configuration of operating parameters, as well as acquires the monitor’s stored blood pressure reading data. These readings are combined with patient demographic entry data to create an ABP report that can be reviewed, edited, stored, confirmed and printed by a physician.

Furthermore, the ABP 92506 RMS application also performs simple summary trending calculations from the individual blood pressure readings to present global statistical results, such as mean and standard deviations for systolic, diastolic, MAP, heart rate and pulse pressure. These are calculated for intervals such as the entire recording period, day, night or period of time as defined by operator.

Finally, the ABP 92506 RMS application can import reports generated by the ABP 90121 RMS and ABP 90219 RMS, predecessors of the ABP 92506 RMS.

The Spacelabs Medical ABP 92506 RMS is designed to comply with the following and Federal Codes:

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21 CFR §11	Applicable Sections of Department of Health and Human Services – Electronic records; electronic signatures
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45 CFR §164	Applicable Sections of Department of Health and Human Services – Administrative requirements
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The ABP 90121 RMS and the ABP 92506 RMS are substantially equivalent in design concepts, technologies, materials and intended uses. The ABP 92506 RMS was developed following a robust software development process, and was fully specified and validated through rigorous testing that, in part, support the compliance of the ABP 92506 RMS to the above mentioned Federal Codes.

The ABP 92506 RMS is the next generation in the Spacelabs Medical ABP RMS family of products.

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JUN - 6 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Datex-Ohmeda, Inc.
Spacelabs Medical
c/o Mr. Al Van Houdt
Director, Regulatory Affairs & Quality
5150 220th Ave SE
Issaquah, WA 98029

Re: K031479

Trade Name: Ambulatory Blood Pressure (ABP) 92506 Report Management System (RMS)

Regulation Number: 21 CFR 870.1130

Regulation Name: Noninvasive blood pressure measurement system.

Regulatory Class: Class II (two)

Product Code: DXN

Dated: May 8, 2003

Received: May 12, 2003

Dear Mr. Van Houdt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

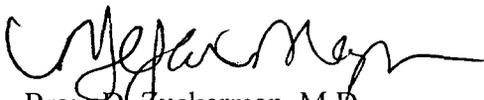
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Bram D. Zuckerman, M.D.

Director
Division of Cardiovascular
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 031479

Device Name: Ambulatory Blood Pressure (ABP) 92506 Report Management System (RMS)

Indications for Use: The ABP 92506 RMS is used to provide data to qualified medical personnel for the purpose of assessing the patient's cardiac health via blood pressure readings taken during daily activity for up to a 48-hour period.

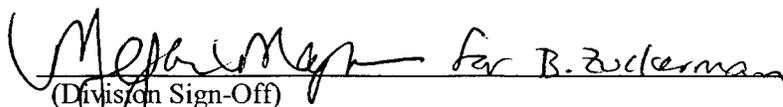
The data is intended to provide preliminary blood pressure data from ambulatory patients for non-time critical applications only.

It is for use in hospitals, clinics or physicians offices by a qualified physician or trained staff member under the supervision of that physician.

Patient diagnosis is not to be performed solely based on the results of this device.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological
Devices

510(k) Number: _____

Prescription Use
(Per 21CFR801.109)

_____ OR Over-The-Counter Use _____

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